

REMARKS

No claims have been added. Claims 17-19 are cancelled. Claims 11, 42 and 44 are amended. Upon entry of this amendment, claims 2, 5, 11, 13-16, 20, 26, 28-31, 42 and 44 are pending in the application.

The amendment to claim 11 further clarifies the steps of the claimed method. The amendment is supported by the specification at, for example, page 3, lines 19-30, page 24, lines 7-32, and page 26 line 13 through page 28, line 21.

Claims 17-19 are cancelled without prejudice and only to progress prosecution of this application. Any proper rejection of claims 17-19 are obviated by this cancellation.

Claims 42 and 44 are amended to recite "of claim 26" as instructed by the Examiner.

Claim 44 is also amended to recite "A method for modulating." The amendment is supported by the specification at, for example, page 23, line 31 through page 24 line 6 and Table 3 which lists the CB1/CB2 binding affinities for a representative number of claimed compounds.

The rejection of claim 11 under 35 USC § 112, 1st paragraph as allegedly failing to comply with the written description requirement.

- The legal burden necessary to properly assert a 35 U.S.C. §112, first paragraph rejection

35 U.S.C. § 112, first paragraph reads:

The specification shall contain (1) a written description of the invention and of the manner and process of making and using it, in such full, clear, concise, and exact terms as (2) to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and (3) shall set forth the best way contemplated by the inventor of carrying out his invention.

The courts have pointed out that "[n]ot every last detail [of an invention need] be described [in a patent specification], else patent specifications would turn into

production specifications, which they were never intended to be." In re Gay, 135 USPQ 311,316 (C.C.P.A. 1962). Citing the opinion in Gay, the Board of Patent Appeals and Interferences echoed this point in its statement that "the law does not require a specification to be a blueprint to satisfy the requirement for enablement under 35 U.S.C. 112, first paragraph," Staehelin v. Secher, 24 USPQ2d 1513, 1516 (Bd. Pat. App. & Int. 1992). Even more broadly, the MPEP states the specification need not disclose what is well known to those skilled in the art and preferably omits that which is well known to those skilled and already available to the public. See MPEP § 2164.05(a)(underlining added).

- The Examiner's Reasoning

In rejecting claim 11 (para. 5 of the Official Action) the Examiner states that,

The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 11 is directed to exciting the cannabinoid compound with electromagnetic radiation; and detecting the electromagnetic radiation. This is new matter since there is no written description in the specification regarding exciting the cannabinoid compound with electromagnetic radiation and detecting electromagnetic radiation emitted by the cannabinoid compound.

As best understood, the Examiner's position is that the specification does not contain any disclosure of fluorescence data for cannabinoid compounds or how such fluorescence data is/would be generated and/or detected.

What the Specification discloses

- Page 21, lines 15-18 expressly define "fluorescence" as "the emission of, or the property of emitting, electromagnetic radiation by a molecule resulting from and occurring only when that molecule is excited by the absorption of radiation."
- Page 33 discloses experimental details of Applicant's fluorescence assay protocol. The specification expressly states that this protocol was used to examine the

fluorescent properties of some of the inventive compounds.

- On page 34 of the specification, Table 2 discloses **fluorescence data** for a representative number of the claimed cannabinoid compounds. The Table includes the Fluorescence Excitation Peak (nm), the Fluorescence Emission Peak (nm), the Stokes' Shift (nm) and the Molecular Extinction Coefficient for each compound.
- On pages 26-28, the specification cites numerous literature references that employ fluorescent ligands or fluorescent compounds in biological systems.

Remarks

The issues of fluorescence, excitation by and emission of electromagnetic radiation in connection with the claimed cannabinoid compounds have been addressed in at least one previous Office Action Response (filed 2/14/05 at pages 46 et seq.). These issues have also been addressed during two telephone interviews with the Examiner and/or his Supervisor (see attached Interview Summary Records for Interviews on 3/30/06 and 4/6/06). Moreover, Applicant has submitted additional references to illustrate that fluorescence generally as well as fluorescence detection methods are well known in the art. (See attached excerpt from Biochemical Calculations pp.346-7 in Response filed 2/14/05) The Biochemical Calculations reference defines the "fluorescence phenomenon" and explains one way that fluorescence is used to measure very low concentrations of fluorescent compounds, i.e. fluorometry.

In light of the data, experimental details, and references disclosed in the specification as well as the knowledge in the art, Applicant respectfully asserts that the specification contains a sufficient written description so as to reasonably convey to one skilled in the art of organic chemistry and/or biochemistry how to excite the claimed

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cannabinoid compounds with electromagnetic radiation and how to detect the electromagnetic radiation emitted by the claimed cannabinoid compounds. Applicant further asserts that given the content of the specification and the knowledge in the relevant art, the amendment to claim 11 in no way constitutes new matter.

Applicant respectfully traverses the rejection and requests that the Examiner withdraw his rejection. If, however, the Examiner maintains his rejection, Applicant respectfully requests that the Examiner explicitly support his reasons for maintaining the rejection in light of the scope and content of the specification and the information known to one skilled in the relevant art.

The rejection of claims 11, 14-20, 26, 29-31, 42, and 44 under 35 U.S.C. §112, 2nd paragraph as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention.

In response to each of the Examiner's § 112, 2nd paragraph rejections, Applicant responds as follows:

- In the rejection of claims 11, 15, 16, 20, 26, 30, and 31, as best understood, the Examiner contends that it is not clear whether Q1 and Q2 and the N atom to which they are attached form the heterocyclic and/or imide ring or whether Q1 and Q2 form the heterocyclic and/or imide ring which is attached to the N. The Examiner also states that the meaning of "imide ring" is not clear and asked whether it is different from a heterocyclic ring.

First, Applicant submits that an imide ring is different from a heterocyclic ring as recited in the claims because an imide moiety will have 3 heteroatoms (2 oxygen and 1 nitrogen) by definition, while the recited heterocyclic ring may have only two heteroatoms—the N to which Q1 and Q2 are attached and another optionally selected from O, N, and S. Thus, it is clear that the claim language should be understood as having Q1 and Q2 together with the N atom to which they are attached as being part of the ring system.

- The Examiner rejected claims 11, 14-16, 20, 26, 29, 30 and 31 alleging that the definition of T2—a substituent group—is not defined.

Applicant respectfully calls the Examiner's attention to the definition of "substituent group" in the specification on page 23, lines 18-30. Because the specification expressly sets forth the definition of for "substituent group" Applicant submits that T2 is not indefinite.

- Claims 17-19 have been cancelled without prejudice and to further the prosecution of this application.
- Claims 42 and 44 have been amended to recite "of claim 26" as instructed by the Examiner.
- Claim 44 has been amended to recite "A method of modulating at least one of the CB1 and CB2 cannabinoid receptors."

Applicant submits that "modulating" a receptor covers both agonist and antagonist activity. Moreover, by reciting "at least one of the CB1 and CB2 cannabinoid receptors" the claim clearly indicates that the method includes compounds that exhibit substantial selectivity (or preference) for modulating one receptor subtype over the other in addition to compounds that modulate both receptor subtypes. Support for the amendment is

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found in the specification at, for example, page 23, line 31 through page 24 line 6 and on page 36 in Table 3 which lists the CB1/CB2 binding affinities for a representative number of claimed compounds.

- Claim 11 is amended to recite additional steps of the method of using a fluorescent compound.

Support for the amendment and for the method is discussed on pages 22 and 23 of this submission. Applicant submits that, as amended, claim 11 recites sufficient active, positive steps that delimit how the claimed use is practiced.

Applicant submits that the amendments discussed above obviate all § 112, second paragraph rejections properly raised by the Examiner.

The rejection of claim 11 under 35 U.S.C. § 101 as allegedly failing to set forth any steps involved in the claimed process/use.

- The Examiner's Reasoning

As best understood, the Examiner rejected claim 11 as not being a proper process claim under 35 U.S.C. § 101.

Remarks

As per the telephone interview with the Examiner on 4/6/06, the Examiner agreed that claim 11 did indeed recite method steps. (see enclosed Interview Summary Record

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for Interview conducted 4/06/2006)

As amended, claim 11 recites three active positive steps involved in the process of using a fluorescent cannabinoid compound. Specifically, the process of claim 11 includes the steps of “providing”, “exciting” and “detecting.”

Because the Examiner has admitted that method steps were indeed present in claim 11, Applicant respectfully requests that the rejection be withdrawn.

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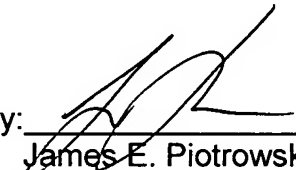
In summary, Applicants have addressed each of the objections and rejections within the present Office Action. It is believed the application now stands in condition for allowance, and prompt favorable action thereon is respectfully solicited.

The Examiner is invited to telephone Applicant(s)' attorney if it is deemed that a telephone conversation will hasten prosecution of this application.

Respectfully submitted,

Alexandros Makriyannis et al

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Atty. Docket: UCONEN/207/US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent application of first named inventor: Alexandros Makriyannis

Application No.: 10/647,544 Examiner: C. AULAKH

Filing Date: 8/25/2003 Group Art Unit: 1625

For: Keto Cannabinoids With Therapeutic Indications

To: Commissioner for Patents, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450

Sir,

INTERVIEW SUMMARY RECORD

Date of interview:

4/6/2006

Type of interview:

telephonic

Participants:

- 1) Examiner C. Aulakh
- 2) Mr. Jim Piotrowski

Exhibit shown or demonstration conducted:

no

Claims discussed:

11

Identification of prior art discussed:

No prior art was discussed.

Description of the general nature of what was agreed to if an agreement was reached, or any other comments:

35 USC §112, first paragraph rejection:

Examiner Aulakh questioned where excitation of a compound by electromagnetic radiation and emission of radiation of electromagnetic radiation by the compound is shown. Mr. Piotrowski indicated that the Table 2 excitation peak values are in nm and in the UV spectrum and the Emission peak values are in nm and are in the UV or Visible spectrum of electromagnetic radiation.

Examiner Aulakh stated that this was a new issue raised in the present Office communication. Mr. Piotrowski indicated that this issue was first raised in an Office communication mailed on 9/14/2004 and was first addressed in a Response filed on 2/14/2005 at pages 46 et seq. Mr. Piotrowski pointed out that the 2/14/2005 Response directed the Examiner's attention to page 21, lines 15-18 of the specification, which explicitly defines fluorescence. Mr. Piotrowski also pointed out how that definition corresponds to the data in Table 2 and to pending claim 11. Examiner Aulakh reviewed the relevant pages of the 2/14/2005 Response and page 21 of the specification. Examiner Aulakh stated that he was not familiar with fluorescence and would discuss this matter with Supervisor Tsang.

35 USC §101 rejection:

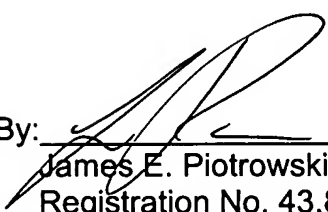
Mr. Piotrowski asked that we next discuss the rejection of claim 11 under 35 USC §101. Examiner Aulakh stated, as far as understood by Mr. Piotrowski, that this rejection was based on a recitation of use with no "use" step. Mr. Piotrowski pointed out that the Office communication rejection is based on "recitation of a use, without setting forth any steps involved in the process." Mr. Piotrowski asked Examiner Aulakh if the clause of claim 11 reciting "providing . . ." was a method step. Examiner Aulakh agreed that this clause was a method step. Mr. Piotrowski then asked, if claim 11 has method steps why is it rejected on the record for not having method steps. Examiner Aulakh indicated that, despite the written record, the rejection was based on, as best understood by Mr. Piotrowski, a lack of use and not on missing method steps. Mr. Piotrowski protested that the Applicant had responded to this rejection as it was applied on the record numerous times and that Examiner Aulakh admitted that claim steps were present in claim 11. Mr. Piotrowski also indicated that Applicant could NOT respond to rejections that were not of record.

Examiner Aulakh suggested adjourning. Mr. Piotrowski suggested discussion of the terms "interacting" and "sample" which were the subject of consecutive rejections and responses. Examiner Aulakh stated he would not consider these rejections at this time and that he would consult with Supervisor Tsang. Mr. Piotrowski stated that he would also call Supervisor Tsang.

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Respectfully submitted,

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